

How to Conduct and Write a Cross-sectional Study

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Cross sectional study design involves observation of variable/s at a particular point in time. It can be descriptive or analytical. Descriptive cross-sectional study design measures prevalence of disease/traits. Analytical cross-sectional study design evaluates associations between variables. However, it could not establish causality.

Doing a cross-sectional study starts with identification of the purpose of the study. This is followed by development of the objectives that should follow the SMART criteria. A dummy table should also be constructed that is based on the objectives of the study so that needed data would not be missed. The next step is defining the population of the study followed by sample size computation which could be done using the Epi-info™ program. Next, selection of sample population, ideally, using random sampling should be done. This is followed by the development of data collection methods. For cross-sectional studies, questionnaires are frequently used to collect data. 5A's of questionnaire development should be kept in mind when formulating the questionnaire. In addition, the use of the following should be avoided: double-barreled item; negatively worded item; statements as questions; agreement response anchors; and too few or too many response anchors.

Data collection and data analysis will be done next. Analysis of data could also be done using the Epi-info™ program. Descriptive statistics which includes frequency distributions, measures of central tendency and measures of variability provide a description and summary of participants data. Specific type of statistics is determined by the type of variable. For analytical type of cross-sectional studies, measure of association could either be Prevalence Ratio (PR) or Odds Ratio (OR). Data independence and type of outcome data measured determine what statistical test to utilize in order to test the hypothesis. The STROBE statement should guide the writing of the final paper.

Key words: Cross-sectional study, descriptive study design, analytical study design

INTRODUCTION

Definition and Types

Cross-sectional study design is one of the four types of observational study design, and it is possibly the most frequently used. In this type of study, observation of variables such as diseases, risk factors, cases, or other types of data, is done at a particular point in time.¹ Researchers will start by selecting or defining the population based on the inclusion and exclusion criteria. Then, data collection will be done using survey questionnaires or analysis of records or existing data at a certain point in time (Figure 1). It is used to study prevalence of diseases, knowledge, beliefs, attitudes, and practices. Prevalence is the proportion in a population at a given time which has the disease, risk factors or other type of problem. It can also be used on public health intervention planning and diagnostic tests validation. It is also used to explore correlation and association of variables like risk factors and

health outcomes prior to establishing a cause- and-effect relationship with case-control or cohort study.²

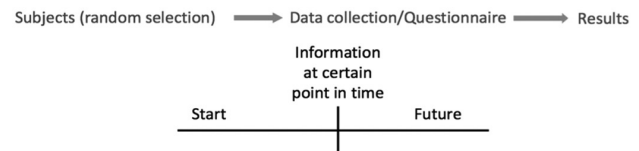


Figure 1. Overview of Cross-sectional Study Design

Cross-sectional study design can be descriptive or analytical. Descriptive cross-sectional study design pertains to estimates of prevalence of disease, traits such as smoking behavior, people's attitudes, knowledge, or health behavior. It can be simply presented as frequencies or percentages. Analytical cross-sectional study designs

on the other hand, assess associations between different variables i.e., association between a risk factor and disease outcome.³

The following are descriptive cross-sectional studies published in The Filipino Family Physician Journal:

1. Awareness, Knowledge, Attitude, Perception and Willingness to Practice telemedicine for Primary Care Consultations among Family and Community Resident and Retainer Physicians from a Community-Based Family Clinic Chain in the NCR, Rizal, Cavite and Laguna.⁴
2. Perceptions, Attitudes and Willingness of Fourth Year Medical Students for AY 2020-2021 on CIM CMSS-DOH Telemedicine Program.⁵

This is an example of an analytical cross-sectional study published in the mentioned journal: "The Association between Perceived Level of COVID-19-Related eHealth Literacy (CoV-eHEALS) and Adherence to Preventive Practices Against COVID-19 Infection Among Adult Patients in Healthway Family Clinics in Marikina and Rizal: An Analytical Cross-Sectional Study".⁶

Advantages and Limitations

Conducting a cross-sectional study is generally faster and inexpensive since it is performed at a particular point in time and there is no need for follow-up. It can be done either before planning or as a baseline in a cohort study. On the other hand, it has several limitations since it is just a one-time determination of exposure and outcome. Using this type of study, it is difficult to derive causal relationships because the temporal link between the exposure and outcome cannot be determined. It also cannot show sufficient disease trends. Furthermore, it is impossible to apply if the disease or risk factor or both are rare.⁷

Steps in Conducting Cross-sectional Study

Step 1 – Identify the Purpose

Before starting any research or study, establishing the purpose or objective is of foremost importance. It may help that researchers ask themselves some questions such as, what do I need to know? Example: Prevalence of COVID 19 infection in healthcare workers. Why do I need to know it? Example: Knowing the prevalence of infection can help in education and disease prevention. What will happen because of this study? Example: Formulate strategies to promote vaccination. Can I get the information from existing sources instead of conducting a survey? Example: COVID infection records or survey. Lastly, which of the following are you aiming to measure: (1) presence of disease or risk factor, (2) knowledge, attitudes, behaviors, and practices, (3) perceptions of knowledge, attitudes, behaviors and practices, (4) association of risk factors to development of disease, and (5) validation of test?⁸

Another important process before conducting research is the literature search or literature scan. It can widen one's knowledge and familiarity regarding the subject. More importantly, it can help the researchers probe if there are already existing studies regarding the topic they want to investigate, identify what is still unknown and therefore establish the objective as to why there is a need to conduct the study.

Step 2 – Develop the Objectives

The general objective states the general purpose or goal of the study such as a general statement of what the results of the study can contribute to health care. After determining the general objective of the study, researchers may proceed with developing the specific objectives. Both general and specific objectives must follow the SMART criteria which stands for Specific, Measurable, Attainable, Relevant and Time bound.⁷ Example: To determine prevalence of COVID 19 infection among healthcare workers in government hospitals in Central Luzon from January to June 2021.

A. Develop the Hypothetical Results (Dummy Tables)

A hypothetical report or a dummy table is a useful guide before doing the data collection. It should be based on the formulated objectives. It can guide the researcher to be focused in formulating the survey or questionnaire so as not to miss out any data. It can also help in developing the sampling frame, sample size and method of sampling. One dummy table corresponds to one specific objective, although others could also be combined. The table below (Table 1) is an example dummy table of a hypothetical study with a general objective of determining prevalence of COVID 19 infection among healthcare workers in government hospitals in Central Luzon.

Table 1. Dummy table for characteristics of healthcare workers who had COVID-19 infection in government hospitals in Central Luzon

	Frequency	Percentage
Gender		
Male		
Female		
Designation		
Physicians		
Nurses		
Nursing Assistants		
Medical Technologists		
Province		
Aurora		
Bataan		
Bulacan		
Nueva Ecija		
Pampanga		
Tarlac		
Zambales		

Step 3 - Define the Population

The entire population can be gathered from national registers or on a sample.³ It is ideal to target the theoretical or whole population, but it is time-consuming and entails additional cost. Hence, a sample or study population that is representative of the whole population is determined to become the study participants. Selection bias can occur if the sample is not representative of the target population.⁸

Defining the population determines what or who should be the study population. The researchers should identify the inclusion and exclusion criteria. Inclusion criteria comprises characteristics or properties needed to be included in the study. On the other hand, exclusion criteria are those who fit the inclusion but should be excluded because the data they might contribute will not be accurate. For a study on the prevalence of COVID 19 infection among healthcare workers in government hospitals in Central Luzon, example inclusion criteria would be "All healthcare workers infected with COVID 19 based on a RT-PCR swab result from an accredited laboratory from January to December 2021 in government hospitals in Central Luzon" while exclusion criteria would be "All healthcare workers who tested positive with rapid antigen only." Bias is present if the study population is wrong or few. To avoid these biases, sample size computation and random selection are very important.¹

Step 4 - Sample Size Computation and Sampling

Sample size estimation ensures the adequacy and balance of sample size so as not to make the study underpowered (too few participants) or overpowered (too many participants).⁹ Epi-info™ is a software tool developed by the United States Center for Disease Control and Prevention (CDC). Other software packages are available for sample size calculation. However, this section mainly discusses the steps using Epi-info™. The program is free and could be downloaded at the following website address: <https://www.cdc.gov/epiinfo/index.html>.

A. Steps in Sample Size Calculation

For the subsequent discussion, we will use the following hypothetical study: A resident wants to determine the prevalence of PAFP members in Luzon who regularly practice motivational counseling. Upon further investigation, the researcher found that the total population of PAFP members in Luzon is 3,000. Prevalence from other studies during review of related literature ranges from 6% to 15%.

1. Launch the Epi-Info software
2. Select STATCALC from the menu of options
3. Select population survey from the menu of options
4. Provide the following information:
 - Population size: Enter 3,000
 - Expected frequency: Enter 10%
 - Acceptable margin of error: Enter 5%
 Design effect and clusters: For simple random sampling, leave design effect and clusters equal to 1. The design effect reflects the

adjustment made to the sample size due to cluster sampling or stratified sampling. The sample size in these sampling methods is usually larger than in simple random sampling. The input in the Clusters is the number of clusters in the population survey. The design effect and clusters are equal to 1 when using simple random sampling. However, the value changes when cluster sampling or stratified sampling is used.¹⁰

The results will appear in the window. Going back to the hypothetical study, the computed sample size is 132 with 95% confidence interval (Figure 2). The sample size determination only serves as a guide. One may consider factors such as cost, potential dropouts, etc. Other investigators add 10% of the computed sample size to account for possible dropouts.

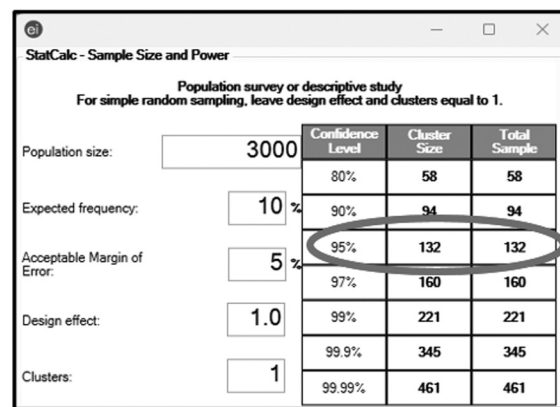


Figure 2. StatCalc Sample Size and Power dialog box with the computed sample size at 95% confidence level highlighted.

B. Sampling

In a cross-sectional study, the best approach for selecting the sample population is random sampling. Chance determines who will comprise the sample. The sampling frame comprises a complete list of the study population. From the sampling frame, simple random or systematic random sampling can be used to select the sample population.¹¹ In simple random sampling, each member has an equal chance of being chosen. For example, the investigator wants to select a sample of 200 from 1,200 employees. She assigns a number to each employee in the institution's database from 1 to 1,200 and uses a random generator to select 200 numbers.¹² Tools such as random number generators in Microsoft Excel can be used. The steps are as follows:

1. Open the Microsoft Excel worksheet and click "data" from the options on the upper tab, then click "data analysis". If the "Data Analysis" tab does not appear follow the following steps: 1. click "file"; 2. go to "options"; 3. click "add-ins"; 4. choose "Analysis ToolPak". The "Data Analysis" tab will appear at the upper right side of the screen.

2. Choose “random number generation”
3. The random number generation box will appear. Fill in the needed information.
4. Click “ok”. The list of randomly selected samples will appear on the excel sheet.

Systematic random sampling is similar to simple random sampling. However, members are chosen at regular intervals. To compute the sampling interval, we divide the population size by the desired sample size. For example: The hospital has a population size of 1,200 employees and a sample size of 200 employees is needed for the study. The sampling interval is computed as 1,200 divided by 200 which is equal to 6. To get the sample from the list of all the employees, a starting point is randomly selected: for example, number 4. Then from number 4 onwards, every 6th person is selected until a sample size of 200 people is completed.¹² In a stratified sampling method, the population is divided into strata (subpopulations) based on certain characteristics such as age range, occupation, social classification, etc. For example, the hospital is composed of 5 divisions: Medical, Nursing, Finance, Ancillary and HOPS. Ensuring that the sample will reflect balance across all employees, we use random sampling to select 20% of the employees under each of the 5 divisions to reach a total of 200 sample population (Figure 3).¹²

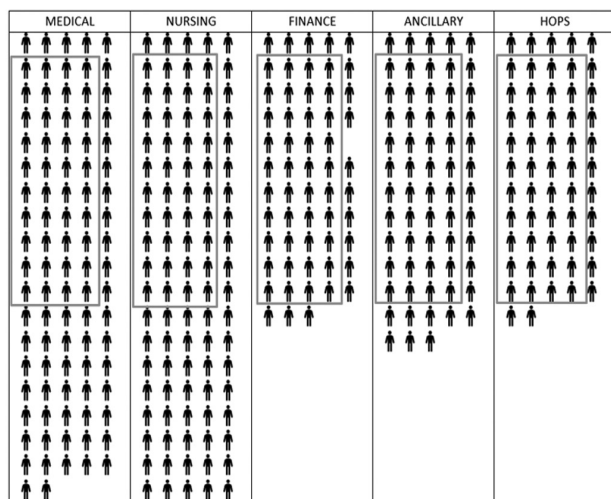


Figure 3. Stratified sampling

Cluster sampling is similar to stratified sampling because the population is also divided into subgroups. However, we randomly select the entire subgroups. For example, Bataan province is composed of 12 towns and city namely: Abucay, Bagac, Balanga City, Dinalupihan, Hermosa, Limay, Mariveles, Morong, Orani, Orion, Pilar, and Samal. We randomly select 5 towns. Then the participants making up the 5 towns will be the sample population (Figure 4).¹²

Step 5 - Develop the Data Collection Method

Data in cross-sectional studies can be collected through interviews, surveys, or observation. Face-to-face surveys yield the best

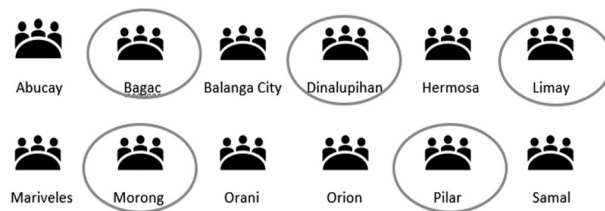


Figure 4. Cluster sampling

result because one can be certain that the participants are the actual respondents, and the investigator can thoroughly explain the questions and choices.⁸ The development of a questionnaire is an important step, especially in cross-sectional studies. One can use the 5 A’s as guide in questionnaire development: Account, Audience, Approach, Ask, and Answer.

1. **Account:** It means description of an event or experience. The first step in developing a questionnaire is to know what the researcher is accounting for. What will the questionnaire measure? Key issues that can be measured are knowledge, cognition, emotion, behavior, attitude, beliefs, practices or intention.¹³ One may conduct a literature review to ensure the relevance of the key issues being measured and to identify existing questionnaires or validated survey scales that can be adapted or used as basis in developing a new questionnaire.¹⁴
2. **Audience.** To be able to formulate the right questions, one must first characterize the audience, in this case, the respondents of the research questionnaire. What type of people will form the survey population? Are the questions appropriate for them? Investigators must take into consideration the characteristics of the respondents such as their age, language proficiency, educational level, and cultural bias. Conducting a field test is helpful for the researchers to clarify some questions and identify potential problems.⁸
3. **Approach:** This pertains to the data collection method to be used. How will the questionnaire be deployed? The researchers must consider the audience, the information asked, and the best way to obtain such information. In a cross-sectional study, common approaches are self-administration and interviews via phone, mail, online or face-to-face.¹⁵
4. **Ask:** This pertains to the questionnaire and the specific questions in it. Self-administered questionnaires can either be answered on paper or via online through the use of platforms such as Google forms (internet-based surveys).

The questionnaire should have a cover letter. This creates the first impression. It includes the introduction, title of the questionnaire, and brief statement about the purpose of the study. To express credibility, investigators may include their names and signatures. It is also important to highlight that the respondent’s participation is crucial for the success of the study

and the estimated time that it may take for the respondent to accomplish the questionnaire. Ensure confidentiality and obtain informed consent. Use simple and specific instructions. Thank the participant at the beginning and end of the questionnaire.^{8,16} Internet-based surveys have become popular because of ease of administration, convenience, low cost, and faster dissemination. Before choosing this method of data collection, the investigators must ensure that the respondents have access to the internet and that they know how to use electronic devices. For internet-based surveys, the first page usually corresponds to the cover letter and informed consent. Questions may be presented in a single scrolling page or in a series of pages. This requires⁷ additional technical skills in creating online questionnaires and using electronic software (i.e., Google form).¹⁶

Questions must be brief and direct. Each question should contain fewer than 20 words, easy to interpret, non-judgmental, and unbiased. Use simple language. Jargons and acronyms must be omitted. Keep the questionnaire as short as possible. The questions must be numbered and organized. They may be grouped on the basis of content (i.e., knowledge, attitudes, skills question). Operational definitions may be inserted as necessary. Prioritize and ask the most important questions earlier in the survey. Instructions must be specific and clear (i.e., put a check mark, shade the circle, skip if not applicable). Define time frames if necessary. For example: instead of “recently,” ask “last week or last month”.^{8,16}

5. Answer: This pertains to the responses. Response formats provide a framework for answering the corresponding survey question. As with formulating the questions, responses should be well-organized, easy to understand, and unbiased. Responses may be “open” (narrative or free text) or “closed” (structured). Open-ended responses may be used but as much as possible at a minimum level. Closed response can be of different formats and may include binary (yes/no), nominal (multiple choice), ordinal (Likert scales), interval and ratio measurements (rating scales).^{8,14} Table 2 illustrates how Likert scales are converted into numbers.¹⁷

Table 2. Example of conversion of five-Likert scales into numbers¹⁷

Options for five-Likert scale	Converting number
Strongly Agree	5
Agree	4
Undecided	3
Disagree	2
Strongly Disagree	1

The answer choices should correspond to the questions, both in content and grammar. One must follow a consistent way of arranging the response items, such as the standard way of reading from left to right and from low to high. Make sure the description of each number

is clear when using a linear scale (i.e., 1 = low, 5 = high). Maintain balance between the “negative” or “low” answer choices and the “positive” or “high” choices on the scale (both in number and degree). The following is an example of a group of choices that should be avoided: great, excellent, super, fantastic, awesome. This should not be done because all choices are “positive” which could lead to bias. Another pitfall is making five degrees of positive choices (i.e., great, excellent, super, fantastic, awesome) and only one “negative” (i.e., terrible). If there is a neutral answer, make the number of choices an odd number to maintain the balance between the “positive” and “negative” choices. On the other hand, if a definite/committing answer is preferred, make the number of choices an even number.⁸ Providing “other” response options or space for other comments or suggestions will help the investigators discover unanticipated answers and new issues, hence an opportunity to improve the questionnaire. Table 3 presents the evidence-based best practices in writing item questions and responses in a questionnaire or survey.¹⁴ Pre-testing and pilot testing are also done to further improve the questionnaire. Pre-testing is done to test one or few elements of the questionnaire, while pilot testing involves the whole process of administering the questionnaire.¹⁸ After which, the questionnaire is subjected to reliability and validity testing.¹⁶

Step 6 – Data Collection and Management

One of the challenges in administering questionnaires for research is the low response rate. The investigator must aim for a response rate of 80% or higher. Several factors have shown to increase response rates: The questionnaire is clear and has a simple layout; questionnaire has been intensively piloted and tested; questions catch and maintain the attention of participants; participants were offered incentives and notified in advance; and the researcher is readily available to clarify some questions and to collect the completed questionnaires.¹⁹ Researchers must keep data in a systematic manner. One may design data collection forms through the use of spreadsheets or database programs. Decide on the software to be used for data entry and analysis (i.e., Microsoft Excel or Microsoft Access). Check for completeness of the collected forms and label all forms with unique identifiers. Then, enter the data in a database or spreadsheet. Check for entry errors. Save all data in files and make back-up files.⁸

Step 7 – Analyze the Data

Descriptive statistics are important components of the results in most studies. Descriptive statistics provide a description and summary of participants data by the provision of significant characteristics of the sample.²⁰ It includes the following: frequency distributions, measures of central tendency and measures of variability.²¹ The type of variable will determine the specific type of statistics to be used.²⁰ Presentation of quantitative data is done as mean and standard deviation while presentation of qualitative or ordinal data is done as frequency distribution and percentage.⁸ As mentioned above, cross-sectional studies could be described as descriptive when the general objective is to determine the prevalence of a disease/condition.²² Prevalence is the proportion of a given population that at the moment of the study

Table 3. Evidence-based best practices in writing item questions and responses in a questionnaire or survey¹⁴

DON'Ts	Survey Example/s (pitfalls)	DO's	Survey Example/s (corrected)
Do not create a double-barreled item	<i>How often do you talk to your nurses and administrative staff when you have a problem?</i>	When you have multiple premises within a given item, either (1) create multiple items for each question that is important or (2) include only the more important question. Minimize the use of conjunctions.	<i>-How often do you talk to your nurses when you have a problem?</i> <i>-How often do you talk to your administrative staff when you have a problem?</i>
Do not use a negatively worded item	<i>-In an average week, how many times are you <u>unable</u> to start class on time?</i>	Make sure "yes" means yes and "no" means no. This generally means wording items positively.	<i>-In an average week, how many times do you start class on time?</i>
Do not use statements as questions	<i>I am confident I can do well in this course</i> <ul style="list-style-type: none"> ● <i>Not at all true</i> ● <i>A little bit true</i> ● <i>Somewhat true</i> ● <i>Mostly true</i> ● <i>Completely true</i> 	Formulate survey items as questions. Questions are more conversational, straightforward, and easier to process mentally. People are more practiced at responding to them.	<i>How confident are you that you can do well in this course?</i> <ul style="list-style-type: none"> ● <i>Not at all confident</i> ● <i>Slightly confident</i> ● <i>Moderately confident</i> ● <i>Quite confident</i> ● <i>Extremely confident</i>
Avoid using agreement response anchors	<i>The high cost of healthcare is the most important issue today.</i> <ul style="list-style-type: none"> ● <i>Strongly disagree</i> ● <i>Disagree</i> ● <i>Neutral</i> ● <i>Agree</i> ● <i>Strongly agree</i> 	Use construct-specific response anchors that emphasize the construct of interest. Doing so reduces acquiescence and keeps respondents focused on the construct in question. This results in less measurement error.	<i>How important is the issue of high healthcare costs today?</i> <ul style="list-style-type: none"> ● <i>Not at all important</i> ● <i>Slightly important</i> ● <i>Moderately important</i> ● <i>Quite important</i> ● <i>Extremely important</i>
Avoid using too few or too many response anchors	<i>How useful was your medical school training in clinical decision making?</i> <ul style="list-style-type: none"> ● <i>Not at all useful</i> ● <i>Somewhat useful</i> ● <i>Very useful</i> 	Use five or more response anchors to achieve stable participant responses. In most cases, using more than seven to nine anchors is unlikely to be meaningful to most respondents and will not improve reliability.	<i>How useful was your medical school training in clinical decision making?</i> <ul style="list-style-type: none"> ● <i>Not at all useful</i> ● <i>Slightly useful</i> ● <i>Somewhat useful</i> ● <i>Very useful</i> ● <i>Moderately useful</i> ● <i>Extremely useful</i>

presents a disease, risk factor and/or other type of problem.¹ When the objective is to determine whether there is a relationship between the study variables, such as an exposure/risk factor and possible outcome/disease, the cross-sectional study is considered analytical.¹

Measure of association for analytical cross-sectional study could either be Prevalence Ratio (PR) or Odds ratio (OR). Recently, the Prevalence Ratio has been increasingly used.²² A 2 x 2 contingency table for cross-sectional studies could be constructed as follows:

Table 4. Two by two contingency table.

	Outcome Present	Outcome Absent	Total
Exposure/Risk Factor Present	a	b	a+b
Exposure/Risk Factor Absent	c	d	c+d
Total	a+c	b+d	a+b+c+d

Prevalence ratio (PR) is calculated as:

PR = Prevalence of outcome among those where the exposure is present / Prevalence of outcome among those where the exposure is absent

$$PR = a / (a+b) \div c / (c+d)$$

The interpretation of Odds Ratio and Prevalence Ratio are the same (Table 5). It should be noted that presence of association does not necessarily mean a causal relationship¹.

Table 5. Interpretation of odds ratio (OR) and prevalence ratio (PR).

Value of OR/PR	Interpretation
Equal to 1	No Association
Less than 1	Negative Association
Greater than 1	Positive Association

Confidence interval (CI) should also be taken into consideration when interpreting OR or PR. When the value of 1 fall within the CI, then there is no significant difference between the groups. Otherwise, the difference between the groups is statistically significant.¹ Decision on what measure of association to use depends on the initial observation of the outcome prevalence in the research and the possible cause and effect relationship between the variables. When the outcome prevalence is greater than or equal to 10%, the PR should be utilized. Otherwise, the OR may be used. However, for cross-sectional studies with analytical objective, it is generally recommended that PR be used as a measure of association. When the causal relationship between variables is reasonable, the PR should be used. But if the causal relationship is unclear, the OR should be used.¹ For cross-sectional studies which are analytical in nature and therefore tests a hypothesis, statistical analysis should be used. Statistical tests to be utilized depends on data independence and type of outcome data measured.²³ In general, results from same individuals or matched individuals are not independent. Statistical tests for paired or matched results are as follows²³:

Table 6. Statistical tests from paired or matched observation.

Variable	Test
Nominal	McNemar's test
Ordinal	Wilcoxon
Quantitative (Discrete or Non-Normal)	Wilcoxon
Quantitative (Normal)*	Paired t test

*It is the difference between the paired observations that should be plausibly normal.

Below is a figure to guide researchers on determining statistical test to use for comparing independent groups²³:

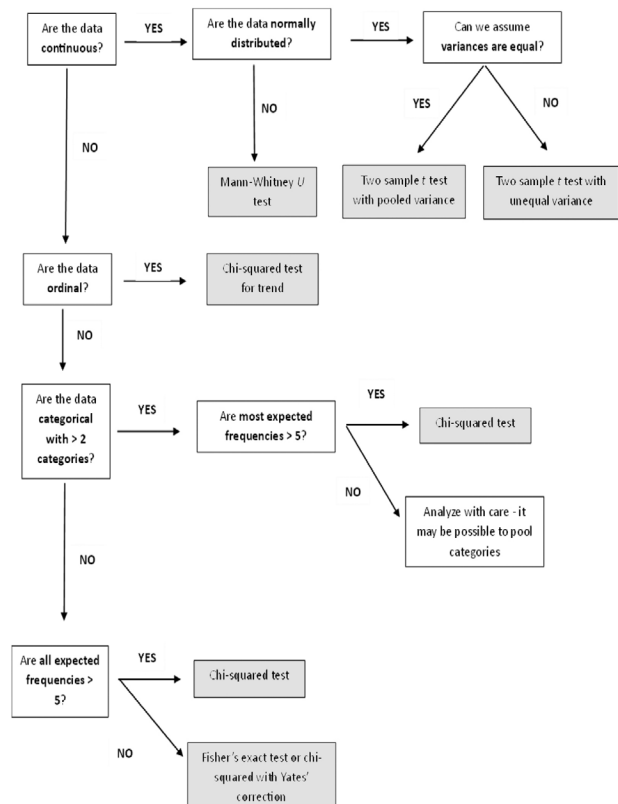


Figure 5. Algorithm to determine statistical test²³

Step 8 – Addressing Ethical Issues

Many epidemiologic studies involve collection of information from participants who will not acquire any personal benefit. Minimal risks to the participants and significant societal benefits must be ensured. Though these studies usually do not cause physical harm to individuals, they still require the participant's attention and time and may affect the individual's right to privacy and confidentiality. Psychological harms and social risks need to be considered. Key areas that need to

be taken in consideration are scientific validity, informed consent, risks and benefits, privacy and confidentiality, sharing of study results with participants, compensation for participants and management of conflict of interest. The research should be done in accordance with the National Ethical Guidelines for Health and Health-Related Research.²⁴

Cross sectional study proposals involving human participants should still be submitted for review for technical and ethical acceptability to one or more scientific review and ethical review committees.²⁵ Template for informed consent form for research interventions that use questionnaires, in-depth interviews or focus group discussions from the

World health Organization is available in the following website: <https://www.who.int/groups/research-ethics-review-committee/guidelines-on-submitting-research-proposals-for-ethics-review/templates-for-informed-consent-forms>.²⁶

Step 9: Writing the Report

Writing the final paper of a cross-sectional study should be guided by the STROBE statement. This is a checklist of items that should be included in reports of observational studies.²⁷

Table 7. STROBE Statement—Checklist of items that should be included in reports of cross-sectional studies.

	Item No	Recommendation
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported
Objectives	3	State specific objectives, including any prespecified hypotheses
Methods		
Study design	4	Present key elements of study design early in the paper
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group
Bias	9	Describe any efforts to address potential sources of bias
Study size	10	Explain how the study size was arrived at
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding
		(b) Describe any methods used to examine subgroups and interactions
		(c) Explain how missing data were addressed
		(d) If applicable, describe analytical methods taking account of sampling strategy
		(e) Describe any sensitivity analyses

Results		
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analyzed
		(b) Give reasons for non-participation at each stage
		(c) Consider use of a flow diagram
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders
		(b) Indicate number of participants with missing data for each variable of interest
Outcome data	15*	Report numbers of outcome events or summary measures
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included
		(b) Report category boundaries when continuous variables were categorized
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses
Discussion		
Key results	18	Summarise key results with reference to study objectives
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence
Generalizability	21	Discuss the generalizability (external validity) of the study results
Other information		
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based

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